34. (New) The implant of claim 27, further comprising a region sized to receive a surgical instrument for facilitating implantation of the implant.

Remarks

Claims 1-34 are submitted for the Examiner's consideration, including amended claims 1, 2, 13, 14 and 16, and new claims 17-34.

Applicants appreciate the Examiner's indication in the Office Action that claim 16 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. In response, claim 16 has been so amended.

The Examiner objected to the Abstract to the extent that the word "invention" is legal phraseology. Applicants have submitted a new abstract herewith. No new matter is believed to have been added.

Claims 2-5, 13 and 14 were rejected in the Office Action under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. In response, claim 2 has been amended to recite that the at least two bone fragments include a first bone fragment with a first coupling portion and a second bone fragment with a second coupling portion, and wherein the first and second bone fragments are joined together by interfitting together the first and second coupling portions. In addition, as suggested by the Examiner, claim 13 has been amended to recite that the hollow body comprises bone tissue selected from the group consisting of autograft, allograft, xenograft bone tissue, and combinations thereof. Applicants submit that these amendments have overcome the indefiniteness rejection for claims 2-5, 13 and 14, and that the rejection should be withdrawn.

Claims 1-15 were rejected in the Office Action under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,123,731 to Boyce *et al.* ("Boyce"). The Office Action stated:

> Boyce et al. discloses an osteoimplant with all the elements of claim 1. See Figures 2 and 3A and columns 7-8, lines 56-10 and column 5, lines 61-67. Each sheet of cortical bone is a bone fragment, and they are mechanically coupled together. They are then cut or machined to form a cylindrically shaped osteoimplant such that the coupled bone fragments are forming a hollow body.

(Office Action, Page 3, lines 22-26).

Applicants' invention, as presented in amended claim 1, is directed to a bone fusion implant for repair or replacement of bone comprising a hollow body with a substantially enclosed hollow region formed between at least two bone fragments which are configured and dimensioned for mutual engagement and which are coupled together.

Boyce is directed to an osteoimplant and method for its production, and discloses that "[t]he osteoimplant can possess one or more cavities which, if desired, can communicate with the surface of the implant through pores, apertures, perforations or channels provided for this purpose." (Boyce, Col. 4, lines 51-54). Boyce further discloses that "[a] cavity can be formed by removing bone material with, for example, a drill, or, alternatively, a cavity can be formed by assembling appropriately configured layers of bone-derived elements." (*Id.*, Col. 8, lines 7-10). However, Boyce is understood to be silent with respect to a substantially enclosed hollow region formed between at least two bone fragments, as recited in independent claim 1.

With respect to dependent claims 2-15 which depend from claim 1, it is submitted that these claims are patentable not only because of the patentability of the independent claim from which they depend, but also for the totality of features recited respectively therein.

In view of the foregoing, it is believed that all the pending claims are in condition for allowance, which is respectfully requested. If the Examiner does not agree, then a personal or telephonic interview is respectfully requested to discuss any remaining issues and accelerate the eventual allowance of the claims.

A fee for an extension of time is believed to be due for this submission and a petition for extension of time is submitted concurrently herewith. A fee sheet is also attached for the presentation of additional claims. Should any additional fees be required, please charge such fees to Pennie & Edmonds LLP Deposit Account No. 16-1150.

Respectfully Submitted,

Seth A. Watkins

FOR: Brian M. Rothery

Date: August 13, 2002

Seth A. Watkins Reg. No. 47,169
For: Brian M. Rothery Reg. No. 35,340
PENNIE & EDMONDS LLP
1667 K Street, N.W.
Washington, D.C. 20006
(202) 496-4400

Enclosures

EXHIBIT B - COPY OF AMENDED CLAIMS (MARKED-UP) AND NEW CLAIMS IN AMENDMENT FILED AUGUST 13, 2002

1. (Amended) A bone fusion implant for repair or replacement of bone comprising a hollow body with a substantially enclosed hollow region formed [from] between at least two bone fragments which are configured and dimensioned for mutual engagement and which are coupled together.

2. (Amended) The implant of claim 1, wherein [at least one bone fragment has] the at least two bone fragments include a first bone fragment with a first coupling portion and [at least one bone fragment has] a second bone fragment with a second coupling portion, and wherein the first and second bone fragments are joined together by interfitting together the first and second coupling portions.

13. (Amended) The implant of claim 1, wherein the hollow body comprises [at least one] bone tissue selected from the group consisting of autograft, allograft, [and] xenograft bone tissue, and combinations thereof.

14. (Amended) The implant of claim 13, wherein the bone tissue of at least one of the bone fragments is partially demineralized or demineralized.

16. (Amended) [The implant of claim 1] A bone fusion implant for repair or replacement of bone comprising a hollow body formed from at least two bone fragments which are configured and dimensioned for mutual engagement and which are coupled together, wherein the hollow body further comprises a completely enclosed hollow region.

17. (New) The implant of claim 16, wherein the at least two bone fragments comprise a first bone fragment with a first coupling portion and a second bone fragment with a second coupling portion, and wherein the first and second bone fragments are joined together by interfitting the first and second coupling portions.

18. (New) The implant of claim 16, further comprising at least one of bone material and bone-growth inducing substance disposed in the hollow region.

19. (New) The implant of claim 16, further comprising cancellous bone with a fluid concentrated therein, wherein the cancellous bone is disposed in the hollow region.

20. (New) The implant of claim 16, wherein the bone tissue of at least one bone fragment is partially demineralized or demineralized.

21. (New) The implant of claim 16, wherein at least one of the bone fragments is at least partially dehydrated to mate with another bone fragment.

22. (New) The implant of claim 16, further comprising a region sized to receive a surgical instrument for facilitating implantation of the implant.

23. (New) The implant of claim 16, further comprising an outer surface with a contour conforming in shape with the end plates of vertebrae.

24. (New) The implant of claim 1, further comprising an outer surface with a contour conforming in shape with the end plates of vertebrae.

25. (New) The implant of claim 1, further comprising an outer surface with a wedge-shaped profile.

26. (New) The implant of claim 1, further comprising a region sized to receive a surgical instrument for facilitating implantation of the implant.

27. (New) A bone fusion implant for repair or replacement of bone comprising:

a substantially enclosed hollow interior space formed between at least two bone fragments which are configured and dimensioned for mutual engagement and which are coupled together; and

an outer surface conforming in shape with the end plates of vertebrae and having at least one migration resistant feature thereon.

28. (New) The implant of claim 27, wherein the at least one migration resistant feature comprises teeth.

29. (New) The implant of claim 27, wherein the at least two bone fragments comprise a first bone fragment with a first coupling portion and a second bone fragment with a second coupling portion, and wherein the first and second bone fragments are joined together by interfitting the first and second coupling portions.

30. (New) The implant of claim 27, further comprising at least one of bone material and bone-growth inducing substance disposed in the interior space.

31. (New) The implant of claim 27, further comprising cancellous bone with a fluid concentrated therein, wherein the cancellous bone is disposed in the interior space.

32. (New) The implant of claim 27, wherein the bone tissue of at least one of the bone fragments is partially demineralized or demineralized.

33. (New) The implant of claim 27, wherein at least one of the bone fragments is at least partially dehydrated to mate with another bone fragment.

34. (New) The implant of claim 27, further comprising a region sized to receive a surgical instrument for facilitating implantation of the implant.